Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)	Centers for Disease Control and Prevention (CDC)
Components of Participating Organizations	Centers for Disease Control and Prevention (CDC), National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP/CDC) at http://www.cdc.gov/ , Division of Nutrition, Physical Activity, and Obesity (DNPAO) at http://www.cdc.gov/nccdphp/dnpao/ Health Resources and Services Administration (HRSA at http://www.hrsa.gov) The Center for Medicare & Medicaid Services (CMS at http://www.cms.gov/), the Administration for Children and Families (ACF at http://www.acf.hhs.gov/index.html)
Funding Opportunity Title	**Affordable Care Act (ACA): Childhood Obesity Research Demonstration**
Mechanism of Support	U18 Research Demonstration – Cooperative Agreements
Announcement Type	New

Funding Opportunity Announcement (FOA) Number	RFA-DP-11-007
Catalog of Federal Domestics Assistance (CFDA) Number(s)	93.535
Category of Funding Activity	Health
FOA Purpose	This Funding Opportunity Announcement (FOA) solicits Research Demonstration Cooperative Agreement (U18) applications for: <u>Component A</u> The objective of the demonstrations is to determine whether an integrated model of primary care and public health approaches in the community can improve underserved children's risk factors for obesity. These approaches may include policy, systems, and environmental supports that encourage nutrition and physical activity for underserved children and their families. Grantees will develop, implement, and evaluate multi-sectoral (i.e., childcare, school, community, health care), multi-level (i.e. child, family, organization, community, policy) intervention demonstration projects for underserved children ages 2-12 years and their families utilizing the Obesity Chronic Care Model and other similar models. The Obesity Chronic Care Model provides a framework to integrate primary care and public health approaches with an intent to guides the design of strategies, approaches, systems, and/or tools to ultimately prevent and reduce childhood obesity. Component A Demonstration Project funded grantees will design, implement, and evaluate the demonstration interventions, with evaluation support from the Component B Evaluation Center funded grantee. Standardized measures across sites will be collected to determine whether the demonstration research project led to changes in preventive services, policy, systems, and environment (e.g. setting, community), and individual outcomes including health, satisfaction, health care utilization and quality of life. <u>Component B</u>

	The results of the Demonstration projects will be used to generate a recommendation that determines whether program components, similar to the awarded demonstration projects, should be implemented nationally for the general population of children who are eligible for child health assistance under Title XXI (CHIP) of the Social Security Act. The Component B funded grantee, the Evaluation Center, will design and conduct the overarching evaluation that will support this recommendation, in collaboration with the Component A Demonstration Project funded grantees and CDC.

Key Dates

Publication Date	January 19, 2011
Letter of Intent Due Date	February 22, 2011 Send LOI to: Michael Dalmat, Dr.P.H. med1@cdc.gov , 770-488-6046 FAX. or FedEx Address: Koger Center-Davidson Building, Room 1098 2858 Woodcock Boulevard Atlanta, GA 30341
Teleconference	Will be held on February 16, 2011 from 4:00-5:30 PM EST. An Amendment to this RFA will be published approximately two weeks before this Teleconference that will provide the Webinar access information.
Application Due Date	**April 8, 2011**, by 5:00 PM Eastern Time. On-time submission requires that electronic applications be error-free and made available to CDC for processing from eRA Commons on or before the deadline date. Applications must be submitted to and validated successfully by Grants.gov/eRA Commons no later than 5:00 PM Eastern Time. **Note:** HHS/CDC grant submission procedures **do not** provide a period of time beyond the application due date to correct any error or warning notices of noncompliance with application instructions that are identified by Grants.gov or eRA systems (i.e., error correction window).

Scientific Merit Review	June 2011
Pre-Decisional Site Visit & Secondary Review	**Pre-decisional Site Visits:** Will be conducted by CDC to more fully understand and validate the capacity of the applicant communities with the highest Scientific Merit Review Scores: Late June 2011 **Secondary Review:** July 2011
Start Date	September 2011
Expiration Date	April 9, 2011
Due Dates for E.O. 12372	Executive Order 12372 does not apply to this program. http://www.cdc.gov/od/pgo/funding/grants/additional_req.shtm#ar7

Required Application Instructions

It is critical that applicants follow the instructions in the SF 424 (R&R) Application Guide except where instructed to do otherwise (in this FOA or in a Notice from the *NIH Guide for Grants and Contracts*). Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions.

Note: The Research Plan is limited to 25 pages.

Applications that do not comply with these instructions may be delayed or not accepted for review.

Note: Up to 10 appendices may be included in the application. Appendices may not exceed 60 pages total. Any pages beyond 60 in the appendices may not be reviewed by the Scientific Merit Review panel members.

Telecommunications for the Hearing Impaired: TTY 1-888-232-6348

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Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

The prevention and reduction of obesity is a priority of the Centers for Disease Control and Prevention (CDC). To this end, the Division of Nutrition Physical Activity, and Obesity (DNPAO), National Center for Chronic Disease Prevention and Health Promotion, engages in a public health approach to improve diet quality, increase physical activity and reduce obesity, including surveillance, applied research, and communications, and supports public health programs that focus on policy, systems, and environmental change in multiple-settings, including childcare, school, worksites, hospitals, and other sectors of the community. This FOA addresses the development of a multi-level and multi-sectoral intervention that links primary care with public heath approaches and promotes behavioral change in conjunction with policy and environmental changes. The National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) of CDC within the Department of Health and Human Services (HHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2020." This RFA addresses "Healthy People 2020" priority area(s) of Focus Area 19: Nutrition and Overweight and Focus Area 22: Physical Activity and Fitness and is in alignment with performance goal(s) to Goal 6, Performance Measure 1(HHS FY 2008 Congressional Justification). For more information go to http://www.healthypeople.gov/ and http://www.whitehouse.gov/omb/mgmt-gpra/. The CDC has identified several priority areas through which measurable impact can be achieved in a short time in key areas of public health. The Division of Nutrition, Physical Activity, and Obesity shares responsibility for the nutrition/obesity priority area.

Within this priority area, CDC is pursuing strategies to:

1. Eliminate artificial trans fat in the food supply;
2. Reduce sodium levels in processed and restaurant foods;
3. Implement nutrition standards for foods marketed to children;
4. Increase consumption of fruits and vegetables;
5. Promote healthy food environments (e.g., discourage unhealthy food and drink consumption in public venues, healthy hospital environments);
6. Provide nutrient information to consumers and improve their ability to use that information to make informed purchases (i.e., front of package, menu, nutrient fact labels); and
7. Increase the number of persons who achieve the physical activity guidelines.

Items 3-7 are directly addressed in this FOA. The goal areas of the CDC's Division of Nutrition, Physical Activity, and Obesity are to: Increase health-related physical activity through population-based approaches; Improve those aspects of dietary quality most related to population burden of chronic disease and unhealthy child development; Decrease prevalence of obesity through prevention of excess weight gain and maintenance of healthy weight loss. A guiding principle of the Division is to reduce health disparities.

Nature of the Research Opportunity

This Funding Opportunity Announcement (FOA) solicits Research Demonstration Cooperative Agreement (U18) applications to:

(1) Develop, implement, and evaluate intervention demonstration projects for underserved children ages 2-12 years and their families that include multiple sectors (at a minimum childcare, school, community, and health care), intervening at multiple-levels (i.e. child, family, organization, community, policy), and utilize the Obesity Chronic Care Model (http://content.healthaffairs.org/cgi/content/abstract/26/2/430) and other similar models. . The objective of the demonstrations is to determine whether an integrated model of primary care and public health approaches in the community such as policy, systems, and

environmental supports for nutrition and physical activity can improve underserved children's risk factors for obesity.

The program design should draw upon promising, innovative models and incentives to achieve measurable outcomes, including reducing obesity-related behavioral risk factors and improved weight status. The design must include policy, systems, and environmental community-oriented activities, child care based activities, school based activities, health care delivery system activities such as those provided by medical providers serving Medicaid/CHIP enrollees, and activities for community health workers (defined as any member of a community or community based organization who provides behavioral counseling or assistance in navigating health care services and community resources). The project is to provide multi-component strategies that promote healthy behaviors for children and their families by providing consistent policy changes on obesity-related behaviors and transforming the environments within which children participate in the community to create safe physical activity opportunities and healthy food access to ultimately improve healthy behaviors and reduce obesity.

(2) Generate a recommendation from implementation and outcome evaluation findings that determines whether programs or program components similar to the awarded demonstration projects could be replicated in a variety of communities to inform decisions about national implementation for children in diverse communities who are eligible for services under Title XXI if they have proven to prevent, reduce, or stabilize obesity in targeted populations.

The goals of this initiative are to create supportive environments and to improve health outcomes including measurable changes in nutrition and physical activity behaviors and in weight status, health care service delivery and utilization, quality of life and satisfaction among children who are eligible for child health assistance under the State child health plans. It is also expected that projects funded under this announcement will impact public health by contributing to the reduction of the overall burden of obesity on society.

Background

Childhood obesity is a major public health problem. Results from the 2007–2008 National Health and Nutrition Examination Survey (NHANES), using measured heights and weights, indicate that an estimated 16.9% of children and adolescents aged 2–19 years are obese (Ogden 2010). Among children aged 2–5 years, obesity increased from 5.0% to 10.4% between 1976–1980 and 2007–2008 and from 6.5% to 19.6% among those aged 6–11. Moreover, racial/ethnic disparities are evident early in life. CDC examined trends and current prevalence in obesity using Pediatric Nutrition Surveillance System (PedNSS) data submitted by participating States, territories, and Indian tribal organizations during 1998—2008 (http://www.cdc.gov/obesity/data/index.html). The findings indicated that obesity prevalence among low-income, preschool-aged children increased steadily from 12.4 % in 1998 to 14.5 % in 2003, but subsequently remained essentially the same, with 14.6 % prevalence in 2008. Despite the overall plateau observed in both NHANES and PedNSS, disparities in recent obesity rates persist among underserved subgroups. In the PedNSS data, prevalence was highest among American Indian/Alaska Native (AI/AN) children (21.2%) and among Hispanic children (18.5%). The Children's Health Insurance Program (CHIP) specifically enrolls children who have been identified to a disproportionate rate of obesity based on socioeconomic status. Furthermore, CHIP also enrolls many minority children and adolescents who are disproportionately burdened by obesity as shown by U.S. surveillance information. As such, there is a well-defined need to target obesity prevention and control interventions among these underserved groups of children enrolled in CHIP.

Obese children are at greater risk for numerous health consequences, including cardiovascular disease and type 2 diabetes. Overweight adolescents have a 70 percent chance of becoming overweight or obese adults (Freedman 2005). Analyses using the Medical Expenditure Panel Survey (MEPS) indicate that obese children and adolescents 6-19 years of age have higher annual medical care and utilization costs compared to normal/underweight children by approximately $3 billion (Trasande 2009).

Recognition that childhood obesity is a major public health problem with a complex network of etiological factors and associated comorbidities has prompted numerous organizations to call for collective efforts to combat the problem from multiple fronts, including innovative research. In 2007, the National Heart, Lung, and Blood Institute (NHLBI) and other NIH Institutes convened a Working Group that recommended that future research on childhood obesity prevention and treatment interventions adhere to the following: careful evaluation designs that explore what is working or not and for whom; be generalizable and have high impact and promise for sustainability; include stakeholders (families, school and environments) in decision making; use qualitative methods to inform intervention design; report on the developmental and design stages of interventions; and include process measures, cost-effectiveness analysis and appropriate statistical analyses (http://www.nhlbi.nih.gov/meetings/workshops/child-obesity/index.htm).

Health care providers, which can include those directly in the clinical setting such as primary care physicians, nurse practitioners, dieticians as well as those individuals who may be part of the medical team but provide outreach to community resources and supports, such as community health workers (CHWs), are uniquely-positioned to help address overweight and obesity, particularly with respect to changing obesity-related behaviors among pediatric patients and their families (Nemet 2005). Support for the use of community-based, multi-disciplinary teams of health care providers to share the responsibility of delivering interventions in this area is clear (Goldstein 2004, Tulloch 2006). Interventions led by health care providers that target behavioral and lifestyle-changes can produce intended changes in risk behaviors among children (Ford 2002, Patrick 2006). Group counseling in children may be more cost-effective and feasible than individual counseling, and has been shown to elicit intended behavior change (Dreimane 2007, O'Connor 2008). Successful counseling initiatives often use patient self-monitoring, self-reward and goal-setting techniques; telephone, internet and mail-based strategies initiated by health care providers have also shown promise among children and adolescents (Saelens 2002, Patrick 2006). CHWs are lay workers based in the community who can play a role beyond the clinic setting by providing additional culturally appropriate counseling or assistance in navigating health care and community services and such as those provided by community agencies, schools, and public health clinics that can result in an augmentation of opportunities for physical activity and nutrition (National Assembly Policy Brief 2006 http://www.nationalassembly.org/fspc/documents/PolicyBriefs/Brief14.pdf, Rosenthal 2010, HRSA Workforce Study http://bhpr.hrsa.gov/healthworkforce/chw/). CHWs have effectively worked within communities to reduce health disparities and improve health outcomes associated with chronic diseases such as diabetes, cardiovascular disease, and asthma (Babamoto 2009, Postma 2009, Fedder 2003). Early evidence has shown that CHWs may be effective when working with families to promote healthful behaviors as a means to ameliorating the burden of childhood obesity (Ayala, 2010, Karanja 2010, Resnick 2009). Ayala et al. (2010) found that after two years, families receiving a promotora intervention focusing on nutrition and physical activity behaviors were more likely than controls to exhibit improvements in parental behaviors, such as controlling and monitoring; parental support; and parent-mediated family behaviors, such as purchasing away-from-home foods and TV watching during dinner time.

Recent initiatives that have included multiple-sectors with policy and environmental change have found promising results in the ability to reduce or stabilize child obesity (Economos et al., 2007, Economos and Curtatone, 2010). Therefore, based on the results of recent behavior change and/or obesity prevention and control interventions that have focused on one setting or level (Knai et al., 2006; The Community Guide), it is evident that a more robust approach is needed that focuses on policy, environmental, and systems approaches. These approaches integrate multiple settings and levels in support of children and their families to improve healthy eating and active living.

Current Research Opportunity

Section 401(a) of The Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA, P.L. 111-3), added new section 1139A, to the Social Security Act (the Act). Subsection 1139A(e) of the Social Security Act requires the Secretary of Health and Human Services (HHS) to conduct a Childhood Obesity Demonstration Project (http://www.ssa.gov/OP_Home/ssact/title11/1139A.htm). In 2010, the Patient Protection and Affordable Care Act appropriated funding for the Project in section 4306.

These projects endeavor to develop a comprehensive and systematic model for reducing childhood obesity among children eligible for services under Titles XIX and XXI of the Social Security Act. Furthermore, these projects will seek to improve health care services delivery and utilization, health outcomes, quality of life and satisfaction among this eligible group of children and their families. This model should include approaches, systems, policies and tools for families to promote healthy behaviors in children by applying strategies using four key components: 1) health care systems and organizations, 2) community health workers, 3) pre-schools (child-care) and schools, and 4) communities.

The Obesity Chronic Care Model (http://content.healthaffairs.org/cgi/content/abstract/26/2/430) (Dietz 2007, Jacobson 2010) and other similar models should aid in designing proposals as part of an application. The Obesity Chronic Care Model is a synthesis of the attributes of the socio-ecological and chronic care models as applied to the prevention and reduction of obesity. The goal is to integrate primary care and public health approaches. The socio-ecological model describes the development of policies and interventions that occur due to actions and interactions across the individual, interpersonal, organizational, community and public policy spheres of influence. The socio-ecological model recognizes the interwoven relationship between individuals and their environment. The chronic care model describes health care for individuals with chronic conditions as taking place in three overlapping arenas: 1) the entire community and its resources and policies; 2) the health care system and payment structures; and 3) the health care provider organization, from large delivery systems to smaller clinics and practices. The Obesity Chronic Care Model is centered on patient self management, and links the environmental spheres, from the individual and family thorough the community and society, with the needed elements of the health system. Within this framework, interventions to improve obesity-related behaviors can be initiated in any setting, and the delivery of the relevant interventions by providers in the health care setting is augmented by policy and environmental changes at large.

In addition to utilizing the Obesity Chronic Care Model, applicants will use self-assessment modalities to identify (a) behavioral risk factors for obesity and (b) needed clinical preventive and screening benefits among identified children on the basis of risk factors. Ongoing support will be provided to identified children and their families to reduce risk factors and promote the appropriate use of preventive and screening benefits. Applicants will be required to design projects intended to improve health outcomes, satisfaction, quality of life, and appropriate use of items and services, including new approaches such as inclusion of community health workers as integral members of health teams or other innovative approaches that are appropriate within the context of the state, for which medical assistance is available under title XIX or title XXI among such target individuals. Additionally, applicants should assess changes in policies, systems and environments through the project design that can improve healthy lifestyles and behaviors in the target group of children and families. This may include strategies included in the CDC Recommended Community Strategies and Measurements to Prevent Obesity in the United States.

Applicants will be required to work across levels and sectors at the individual, family, organizational, and community levels to provide a range of coordinated interventions that include services, approaches, systems, tools, programs, and policies across multiple sectors related to reducing childhood obesity. Applicants must draw upon promising, innovate models to develop these interventions. These services and interventions must include community-based activities; childcare and school-based activities; providing screening, educational, counseling activities through the local health care delivery system. Applicants are encouraged to collaborate with providers serving Medicaid/CHIP enrollees. The community-wide consortium should include partners from the multiple sectors with linkages to relevant members across the community who are working towards policy and environmental changes including available healthy food and physical activity in the community and youth settings. Useful tools that can be employed by local consortia/collaborative can be found in toolboxes like the one found in the web site http://ctb.ku.edu/en/tablecontents/chapter_1003.aspx.

This project will be expected to work in concert and demonstrate linkage with current federal efforts addressing childhood obesity prevention and reduction that are already present in the community, including those noted in the White House Task Force on Childhood Obesity Report. Examples of these federal efforts include those occurring through current CDC supported state programs including the Nutrition, Physical Activity and Obesity State program

(http://www.cdc.gov/obesity/stateprograms/index.html), CDC supported community programs such as Healthy Communities (http://www.cdc.gov/healthycommunitiesprogram/), The Racial and Ethnic Approaches to Community Health (REACH) (http://www.cdc.gov/reach/) and the recently American Recovery and Reinvestment Act (ARRA) Communities Putting Prevention to Work (CPPW) State, Territorial, Tribal and Community programs administered through the CDC, programs of the Department of Education and United States Department of Agriculture, and the Healthy Weight Collaborative initiative administered through the Human Resources and Services Administration (HRSA). Initiated in 2010, CPPW funds more than 45 communities and all 50 states to change food and physical activity environments, particularly through the use of policy. Many of these programs are working to improve the child care and school nutrition and physical activity environments (http://www.cdc.gov/CommunitiesPuttingPreventiontoWork/). The Healthy Weight Collaborative of HRSA was funded in 2010 to share evidence-based and promising community-level and clinical interventions to prevent and treat obesity. Through the Healthy Weight Collaborative, collaborative teams are being recruited to help states and local communities develop practical approaches that link public health and primary care. Furthermore, HHS recently announced the first in a series of awards under the Affordable Care Act designed to address pressing construction and renovation needs in community health centers across the country and expand access to quality health care. Efforts are underway to improve the infrastructure, expertise and services needed to improve health care across the country. The Center for Medicare & Medicaid Services (CMS) expects to issue future guidance to program directors on State Medicaid and CHIP coverage and reimbursement for childhood obesity related services.

In addition to working in concert with these other federal efforts, this project could complement non-governmental efforts, augmenting state obesity task force activities and initiatives like the Robert Wood Johnson Foundation's Healthy Kids, Healthy Communities initiative (http://www.rwjf.org/childhoodobesity/pg.jsp) and the work of state and community Food Policy Councils and Community Coalitions (http://www.foodsecurity.org/).

This research demonstration project is an opportunity to evaluate whether benefits covered under titles XIX (Medicaid) and XXI (CHIP) of the Social Security Act are having an impact on improving parenting strategies, parent modeling, and child health outcomes, such as quality of life and changes in obesity related behaviors such as nutrition (increase fruit and vegetables, decrease sugar drinks, decrease energy dense food consumption), screen time/television viewing, and sleep and physical activity. To augment and sustain improved health outcomes, appropriate and effective interventions in community settings (e.g., childcare, school), and at different levels (e.g., family, community organizations) are needed to prevent and reduce not only behavioral, but also environmental risk factors for obesity as suggested by the Expert Committee Recommendations Regarding the Prevention, Assessment, and Treatment of Child and Adolescent Overweight and Obesity. This approach supports the recruitment and engagement of parents and other influential adults as "change agents" within and outside of the family. These individuals interact with the child in diverse settings that span the continuum of childhood activities and safe environments in concert with changes in policies, environments and best practices in child care, schools and communities (e.g. such as improving safe physical activity in neighborhood parks, recreation centers) that reinforce and complement efforts to increase fruit and vegetable consumption and physical activity and decrease passive screen time, consumption of high energy dense foods and sugary beverages.

Scientific Knowledge to be Achieved through this Funding Opportunity

The objective of the demonstrations is to determine whether an integrated model of primary care and public health approaches in the community such as policy, systems, and environmental supports for nutrition and physical activity can improve underserved children's risk factors for obesity. This includes changes in factors such as improved parenting skills, reduced childhood obesity risk factors such as improved physical activity, sleep, fruit and vegetable intake, reduced television and screentime viewing, high energy dense foods and sugar drink consumption, improved utilization of preventive services such as screening and counseling, improved satisfaction with health care services provided by Federally qualified health centers and other primary care providers in the community, and improved quality of life.

The research demonstration projects and accompanying overarching evaluation supported by this FOA are expected to generate knowledge that can be translated into models that can be developed, implemented, sustained and brought to scale to benefit the general population of children who are eligible for child health insurance assistance under State Children's Health Insurance Programs (CHIP). The demonstration should draw upon promising, innovative models and incentives to reduce behavioral risk factors. The purpose is to utilize what is learned from these demonstration projects to implement similar cost-effective programs or program components to improve health outcomes for underserved children including obesity-related nutrition and physical activity behaviors, improve health care services delivery and utilization, quality of life and satisfaction.

Funded childhood obesity prevention and reduction demonstration projects should:

- Ensure delivery of appropriate primary care preventive services to underserved children including where possible inclusion and collaboration with medical providers serving Medicaid/CHIP enrollees.

- Focus on underserved families of children aged 2 to 12 to improve parenting strategies, parent modeling, and children's behavioral risk factors.

- Provide educational, counseling, promotional, training and outreach efforts to families through the local health care delivery systems. These efforts should utilize multidisciplinary health care teams.

- Include community health workers as members of the health teams and should be trained through and supervised by qualified health professionals to deliver appropriate educational and counseling efforts. Community health workers can also facilitate linking families and their children to appropriate community resources and can work toward healthy community development.

- Identify and integrate into the project design school, child care, and community activities including policy, environmental, and systems change approaches that have sustainability.

- Identify and build upon existing community, regional and state resources, relationships and assets.

- Ensure consistent messaging across the interventions.

Research Objectives and Approach

NOTE
This is not a capacity development cooperative agreement. Successful applicants must have the capacity in place to rapidly initiate the demonstration, sustain systems and policy changes, and to participate in the evaluation of its effectiveness (reach, coverage, adoption of new provider and family behaviors, changes in service utilization, etc.). Evidence of this capacity will be used to confirm eligibility (see Section III. Eligibility Information, 4. Additional Information on Eligibility). Also, Pre-decisional Site Visits will be conducted by CDC to validate the readiness of applicants and their communities to participate in this research demonstration.

This FOA Has Two Components, A and B: Applicants must specify which Component they are applying. Component A solicits applications to participate as a Demonstration Project. Component B solicits applications to serve as the third-party evaluator (the Evaluation Center) that will collaborate with CDC and the participating Demonstration Projects in all aspects of the overarching evaluation of all the research demonstration projects. Applicants may apply for either Component A or Component B, but not both.

As outlined in the Children's Health Insurance Program Reauthorization Act, successful applicants are those: (A) that demonstrate that they have previously applied successfully for funds to carry out activities that seek to promote individual and community health and to prevent the incidence of chronic disease and that can cite published and peer-reviewed research demonstrating that the

activities that the entities propose to carry out with funds made available under the grant are effective; (B) that will carry out programs or activities that seek to accomplish a goal or goals set by the State in the Healthy People 2010 plan of the State; (C) that provide non-Federal contributions, either in cash or in-kind, to the costs of funding activities under the grants; (D) that develop comprehensive plans that include a strategy for extending program activities developed under grants in the years following the fiscal years for which they receive grants under this subsection; (E) located in communities that are medically underserved, as determined by the Secretary; (F) located in areas in which the average poverty rate is at least 150 percent or higher of the average poverty rate in the State involved, as determined by the Secretary; and (G) that submit plans that exhibit multi-sectoral, cooperative conduct that includes the involvement of a broad range of stakeholders, including— (i) community-based organizations; (ii) local governments; (iii) local educational agencies; (iv) the private sector; (v) State or local departments of health; (vi) accredited colleges, universities, and community colleges; (vii) health care providers; (viii) State and local departments of transportation and city planning; and (ix) other entities determined appropriate by the Secretary.

Research Demonstration Project Plan and Objectives (Component A):

Successful applicants who will receive awards are expected to:

1. Provide a plan for their intervention program approach developed with the involvement of key sector and community stakeholders, which identifies current gaps, barriers, and opportunities through a community assessment, as well as current child and family attitudes and behavioral risk factors.

2. Project design should utilize the Obesity Chronic Care Model and include:
    a. A definition of eligible participants in the study focusing on underserved children aged 2-12 years with adequate power to detect changes in utilization, behavior and satisfaction, over the period of intervention.

    b. Critical information about community assets and needs, and a plan to complete a comprehensive Community Assessment that will fill information gaps.

    c. The design of a multi-sectoral and multi-level intervention strategy.

    d. A preliminary site-specific evaluation research design and protocol with the expectation of collaboration and revision of preliminary research plan with other demonstration project sites, evaluation center, and CDC to ensure common evaluation measures across sites, and plans for finalizing evaluation methods, and obtaining appropriate approvals (e.g., IRB).

    e. A plan for sustaining the intervention or specific intervention components post-evaluation, and expanding it beyond the demonstration catchment area. The former, if it entails adding, altering or augmenting basic covered services, would need a request to CMS for approval. This could also include examples of non-financial commitment and agreement from their state Medicaid/CHIP agency and contracting insurers who work with the state to deliver CHIP.

3. Design and implement a plan for linking levels and sectors, including, but not limited to communications, referrals, and reporting.

4. Design and implement a project that is intended to assess measurable changes in risk factors for obesity and improved outcomes including:

    a. Identifying, through self-assessment (self-report by child and/or caregiver), behavioral risk factors for obesity among children;

b. Identifying, through self-assessment, needed clinical preventive and screening benefits among those children identified as target individuals on the basis of such risk factors;
c. Providing ongoing support to such target individuals and their families to reduce risk factors and promote the appropriate use of preventive and screening benefits; and
d. Improving health outcomes, satisfaction, quality of life, and appropriate use of items and services for which medical assistance is available under title XIX or title XXI among such target individuals;
e. Improving policies, systems and environmental changes to promote healthy lifestyles and behaviors among the target group of children and their families.

5. Implement the demonstration project:

    a. Lead and coordinate the consortium or coalition as it implements the intervention.

    b. Collect and analyze baseline, interim, and follow-up data using common measures (across demonstration sites) that can be used to measure expected changes in behaviors and weight and to support recommendations and reporting about the intervention. (More specific outcome measures are described in the section below, Research Plan Components, Component A, (h) Evaluation Research Design.)

6. In collaboration with the Evaluation Center and CDC, contribute to the overall evaluation of this initiative by:

    a. Collecting and sharing demonstration project process and outcome data with the Evaluation Center.

    b. Capturing and documenting lessons learned, including, but not limited to practical keys to sustainability and local or state scalability based on documented experience that can inform national implementation.

    c. Preparing actionable recommendations as to whether the demonstration project or components should be continued and, if so, how it could be sustained locally or expanded to other communities.

    d. Developing guidelines for transferring lessons learned to other communities.

Timeline (Component A):

Phase 1: Start-up (Months 1-12).
In collaboration with the Evaluation Center and CDC:

a. Complete the Community Assessment so that gaps in information are filled, and use the results to inform project design.

b. Finalize the intervention design with partners and stakeholders.

c. Work with the Evaluation Center and CDC to finalize overarching evaluation questions, the evaluation research design for the overarching evaluation and the demonstration project evaluation, finalize cross-grantee indicators and data collection instruments in support of measurable outcomes and for the overarching evaluation, and a coordinated work plan and timeline.

d. Complete the study participant recruitment and retention plan.

e. Train community health workers.

f. Establish infrastructure and system for coordination between levels and sectors, including, but not limited to communications, referrals, and reporting.

g. Finalize the work plan (timeline, clarification of responsibilities, milestones, reporting).

Phase 2: Intervention Implementation (Baseline, Interim, and Follow-Up Data Collection) (Months 13-36)

Phase 3: Finalize data collection, Work with Evaluation Center on the Evaluation and Reports, Assess Sustainability, Use results to strengthen the program (Months 37-48)

a. Finalize local demonstration project data analysis, interpretation of findings, development of local recommendations for strengthening the intervention, and lessons learned that can be used to guide interventions in other communities.

b. Participate in the final analysis of data, interpretation of findings, and preparation of recommendations related to the overarching evaluation.

c. Use evaluation findings and recommendations to strengthen and sustain the intervention program.

d. Provide the Evaluation Center with assistance in scheduling post-intervention implementation interviews.

Evaluation Center Research Objectives (Component B):

The successful applicant is expected to:

1. Assist in the design of common community assessment methods and tools for use by each demonstration project community (e.g., CDC Recommended Community Strategies and Measurements to Prevent Obesity in the United States).

2. Design and implement an overall evaluation plan that determines whether programs similar to the awarded demonstration projects should be implemented nationally for children in diverse communities who are eligible for services under Title XXI. The overall evaluation plan should be consistent with that of an impact evaluation design.

3. Collaborate with demonstration projects and CDC to develop and coordinate community-specific evaluation protocols to systematically assess the effectiveness of the research demonstration projects, separately and across projects.

4. Serve as an evaluation research data repository for the overall evaluation of this initiative and the demonstration projects' evaluations.

5. Compile and analyze data; distill evaluation research findings; and interpret these findings to support (1) national policy decision-making and (2) local community decision-making to solidify, sustain, and expand the program.

6. Produce interim progress reports to update demonstration project staff, CDC, and others.

7. Produce a final evaluation report that incorporates the results of the overall evaluation research and the demonstration projects and provides detailed analysis on health outcome changes, specifically changes in BMI.

Timeline (Component B)

Phase 1: Evaluation Research Design, Coordination, and Infrastructure (Months 1-12)

1. In collaboration with funded Demonstration Projects and CDC:

    a. Clarify roles, responsibilities, timelines, and contributions of all parties with respect to the evaluation research for the overall initiative and the demonstration projects.
    b. Finalize the data collection plan and instruments and obtain approvals (e.g., IRB).
    c. Collect and/or support the collection of data and information in demonstration project communities.
    d. Finalize the design and start implementing the evaluation research plan for the overall initiative.
    e. Prepare for and begin functioning as the Evaluation Research Data Repository.

Phase 2: Evaluation Research Data Collection, Analysis, Preliminary Findings, and Use of those Findings Locally (Months 13-36)

In collaboration with the Demonstration Projects, and in consultation with CDC:

Complete the process and outcome evaluation including health outcomes such as quantifiable changes in behavior and weight outcomes, and cost- effectiveness, cost savings, and scalability analyses. (More specific outcome measures are described in the section below, Research Plan Components, Component A, (h) Evaluation Research Design.)

Phase 3: Finalize data collection, the overarching evaluation and produce reports, including assessments of sustainability and scalability (Months 37-48)

a. Finalize data aggregation and synthesis incorporating data and information from all demonstration sites.

b. Conduct post-intervention key informant interviews in each demonstration project community.

c. Lead the process of interpreting findings, developing recommendations, and incorporating what has been learned into draft guidelines for policy makers and communities.

NOTE:
Provide a detailed design, work plan, and timeline in Section IV, Research Plan Components.

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Section II. Award Information

Funding Instrument	Cooperative Agreement: A support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, scientific or program staff will assist, guide, coordinate, or participate in project activities.
Application Types Allowed	New
Funds Available and Anticipated Number of Awards	**Component A (Demonstration Projects)** It is It is anticipated that 3 awards will be made and that a total of $5.25 million will be awarded in the Budget Years 1, 2, and 3, with an average award of $1.75 million per Demonstration Project. It is anticipated that a total of $3.075 million will be awarded in Budget Year 4, with an average award of $1.025 being made per Demonstration Project. These estimates include direct and indirect costs. Awards issued under this FOA are contingent on the availability of funds and submission of a sufficient number of meritorious applications. **Component B (Evaluation Center)** It is anticipated that one award will be made for this component, and that up to $1 million will be awarded to the Evaluation Center in Budget Year 1-3, and $1.25 in Budget Year 4. These estimates include direct and indirect costs.

	Awards issued under this FOA are contingent on the availability of funds and submission of a sufficient number of meritorious applications.
Ceiling and Floor of Individual Award Range	**Component A: Demonstration Projects** The total 4-year award for Component A Demonstration Projects may not exceed $5.25 million per Demonstration Project. If you request a funding amount greater than this ceiling for the 4-year award, your application will be considered non-responsive, and will not be entered into the review process. You will be notified that your application did not meet the submission requirements. **Component B (Evaluation Center)** The total 4-year award for the Component B Evaluation Center may not exceed $4.25 million. If you request a funding amount greater than this ceiling for the 4-year award, your application will be considered non-responsive, and will not be entered into the review process. You will be notified that your application did not meet the submission requirements.
Project Period Length	The first Budget Period will start on September 29, 2011 and end on September 28, 2012. The Project Period will start on September 29, 2011 and end on September 28, 2015 (four years). Throughout the project period, CDC's commitment to continuation of awards will be conditional on the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports), and the determination that continued funding is in the best interest of the Federal government.

HHS/CDC grants policies as described in the HHS Grants Policy Statement will apply to the applications submitted and awards made in response to this FOA.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions:

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

The following types of Higher Education Institutions are always encouraged to apply for CDC support as Public or Private Institutions of Higher Education:

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)

- Alaska Native and Native Hawaiian Serving Institutions

Nonprofits Other Than Institutions of Higher Education
- Nonprofits (Other than Institutions of Higher Education)

For Profit Organizations
- For-Profit Organizations

Governments
- State Governments including State Health Departments
- County Governments including Local Health Departments
- City or Township Governments
- Special District Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)
- Eligible Agencies of the Federal Government
- U.S. Territory or Possession

Other
- Federally Qualified Health Centers
- Health Care Providers
- Faith-based or Community-based Organizations
- Native American tribal organizations (other than Federally recognized tribal governments)
- Regional Organizations
- Established consortia or partnership of entities
- Bona Fide Agents

A Bona Fide Agent is an agency/organization identified by the state as eligible to submit an application under the state eligibility in lieu of a state application. If applying as a bona fide agent of a state or local government, a legal, binding agreement from the state or local government as documentation of the status is required. Attach with "Other Attachment Forms" when submitting via www.grants.gov.

Required Registrations

Applicant organizations must complete the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. Applicants must have a valid Dun and Bradstreet Universal Numbering System (DUNS) number in order to begin each of the following registrations.

- Central Contractor Registration (CCR) – must be renewed annually
- Grants.gov
- eRA Commons

All Program Directors/Principal Investigators (PD/PIs) must also work with their institutional officials to register with the eRA Commons or ensure their existing eRA Commons account is affiliated with the eRA Commons account of the applicant organization.

All registrations must be successfully completed and active before the application due date. Applicant organizations are strongly encouraged to start the registration process at least four (4) weeks prior to the application due date.

Eligible Individuals (Project Director/Principal Investigator) in Organizations/Institutions

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Project Director/Principal Investigator (PD/PI) is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for HHS/CDC support.

For institutions/organizations proposing multiple PDs/PIs, visit the Multiple Program Director/Principal

Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the SF 424 (R&R) Application Guide.

3. Cost Sharing

This FOA does <u>not</u> require cost sharing such as in-kind time from the stakeholder groups as defined in the HHS Grants Policy Statement. However, cash or in-kind contributions to fund activities under the awarded grants are encouraged.

4. Additional Information on Eligibility

Number of Applications

Only one application per institution (normally identified by having a unique DUNS Number) is allowed.

HHS/CDC will not accept any application in response to this FOA that is essentially the same as one currently pending initial peer review unless the applicant withdraws the pending application. HHS/CDC will not accept any application that is essentially the same as one already reviewed.

<u>Applicants for Component A, Demonstration Projects, must:</u>

Provide evidence of applicant eligibility for each of the following criteria in Appendix 1:

(A) The applicant demonstrates its reach into the eligible pool of children for this FOA, focusing on low income children in a specified catchment area:
-- Eligible for services under titles XIX and XXI of the Social Security Act;
-- Children and their families living at least 150% or higher federal poverty level; or
-- Catchment areas where 50% of students are in schools are eligible for the National School Lunch Program. See Census Bureau's American Fact Finder page: http://factfinder.census.gov

(B) The applicant provides documented evidence from prior experiences that demonstrates the ability to recruit and retain underserved children and their families throughout a demonstration.

(C) The applicant proposes strategies for engaging and linking (a) children and their families to key organizations (to include, but not limited to health care, community health workers, childcare, and schools) and (b) key organizations to each other (to include, but not limited to health care, community health workers, childcare, and schools).

(D) The applicant includes at least one of each type of strategy (policy, systems, and environmental) to promote and reinforce healthy behaviors in each of at least four sectors (to include, but not be limited to health care, child care, school, and community).

(E) The applicant provides formal documentation that the public health and health care delivery systems have committed to the project and its goals, including the state and/or local public health department, key health care provider organizations, and state Medicaid/CHIP agency.

(F) The applicant documents that a cadre of trained community health worker is available to serve the children and families in the catchment area and to participate in the demonstration project.

<u>Applicants for Component B, Evaluation Center, must:</u>

Provide evidence of applicant eligibility for each of the following criteria in Appendix

1:

(A) The applicant demonstrates and documents experience in conducting complex evaluations of research in childhood obesity or similar research questions as those solicited by this FOA, including process and outcome measurement and evaluation.

(B) The applicant demonstrates and documents that the proposed evaluation team leader/manager has a minimum of five years of experience leading and managing complex evaluations, and a minimum of 5% of this person's time is committed to leading this project.

If your application is incomplete or non-responsive to the special requirements listed in this section, it will not enter into the review process.

Section IV. Application and Submission Information

1. Obtaining an Application Package

Applicants must download the SF424 (R&R) application package associated with this funding opportunity from Grants.gov.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the SF424 (R&R) Application Guide, except where instructed in this funding opportunity announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

Letter of Intent

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to estimate the potential review workload and plan the review.

By the date listed in Part 1. Overview Information, **February 22, 2011**, prospective applicants are asked to submit a letter of intent that includes the following information:

Descriptive title of proposed research
Name, address, and telephone number of the PD(s)/PI(s)
Names of other key personnel
Participating institutions
Number and title of this funding opportunity, and specification of the component (A or B)

The letter of intent should be sent to:

Michael E. Dalmat, Dr.P.H.
Extramural Research Program Office
National Center for Chronic Disease Prevention and Health Promotion
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services
4770 Buford Hwy, N.E., M/S K-92
Atlanta, GA 30341
Telephone: (770) 488-6423
Fax: (770) 488-8046
Email: med1@cdc.gov

FedEx address
Koger Center-Davidson Building
2858 Woodcock Blvd.
Atlanta, GA 30341

Required and Optional Components

A complete application has many components, both required and optional. The forms package associated with this FOA in Grants.gov includes all applicable components for this FOA, required and optional.

Page Limitations

All page limitations described in this individual FOA must be followed.

For this FOA, the Research Strategy section is limited to 25 pages.
The length of the Research Plan (Research Strategy) must not exceed 25 pages.

Research Plan Components

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

The research plan should include:

Component A

1. A plan for the intervention program and evaluation research approach developed with the involvement of key sector and community stakeholders including health care providers serving Medicaid/CHIP enrollees, which incorporates information about current gaps, barriers, and opportunities, that specifies how they will be addressed. This should describe:

   1) Coordination with and augmentation of existing efforts. This should include detailing how the proposed project will coordinate, complement, and/or augment existing federal and nonfederal funding efforts and resources related to improvements in nutrition, physical activity, and obesity.

   2) Enacted and in-process policies, environments, and activities that address improved nutrition and physical activity in the multiple sectors.

   3) Current community-wide partnerships or consortia engaged in improvements in the built environment or obesity prevention and control.

   4) The health literacy level of the population to be addressed and ways to address.

   5) Prior assessment of the behavioral risk factors for obesity and attitudes among the population of underserved children and their families. This will be used to determine priority support strategies to reduce risk factors and promote appropriate use of preventive and screening benefits by health care providers and CHWs.

   Examples of community assessments and assessment tools can be found at the web site http://ctb.ku.edu/en/tablecontents/chapter_1003.aspx.

2. Project intervention design. The intervention design can utilize the Obesity Chronic Care Model, (http://content.healthaffairs.org/cgi/content/abstract/26/2/430), a model that integrates primary care and public health approaches, as a framework for guiding the design of strategies, approaches, systems, and/or tools. Additionally, the design must include the following:

   a) Multi-level: Implement an intervention to work at the individual, family, organizational, community, and policy and environmental levels to provide a range of coordinated services and interventions related to improving obesity-related behaviors such as nutrition (e.g. increase fruits and vegetables and decrease sugar drinks and energy dense foods),

decrease passive screentime and television viewing, and increase sleep and physical activity among underserved children located in areas in which the average poverty rate is at least 150 percent or higher of the average poverty rate in the state involved.

b) Multi-sector: Implement or sustain activities directed at changing policies and environments in all key sectors including appropriate clinical preventive, screening, and counseling services with provision of educational and training activities by providers and/or CHWs. Changes in all sectors should be based on policy change, policy enforcement, or environmental change carried out in the key settings related to nutrition, physical activity and other risk factors for obesity: (a) childcare, (b) school, and (c) other community-based activities. The applicant should specifically carry out educational, counseling, promotional and training activities through the local health delivery systems that are integrated with the efforts of the other sectors.

c) Preserve a focus on underserved children ages 2-12 years and their families and their behavioral risk factors as ascertained through assessment (i.e. interview, screening, surveys). Ensure that their approach meets the needs of (1) populations disproportionately impacted by obesity (e.g. racial and ethnic minorities or low socioeconomic status populations); (2) persons with disabilities; and/or (3) cultural and linguistic diversity. Include a description of recruitment and retention approaches that will be used during the study period.

d) Specifically address and incorporate: (1) the use of self assessments to identify risk factors for obesity among children; (2) the use of self assessment to identify needed clinical preventive and screening benefits among identified children; (3) provision of ongoing support for identified children and their families to reduce risk factors and promote the appropriate use of preventive and screening benefits; (4) assessing health outcomes, including satisfaction, quality of life and appropriate use of items and services children and their families are eligible for under title XIX or under title XXI; and (5) changes in policies, systems and environments that promote healthy lifestyles and behaviors among eligible children and their families.

e) The integration of traditional and non-traditional CHWs for education, counseling and outreach to community opportunities for children and their families. CHWs should be trained and supervised by qualified health professionals. CHWs may use motivational interviewing, targeted feedback in the home or community setting, and through technology or through individual/group educational sessions to promote effective parenting strategies around rules and key behaviors. CHWs may also help children and families connect to social support groups to aid families in initiating and maintaining healthy behaviors, and community referrals related to nutrition and physical activity. CHWs may utilize existing health education materials such as *We Can*! (http://www.nhlbi.nih.gov/health/public/heart/obesity/wecan/health-professionals/index.htm). These strategies must be tailored to the local context (economic, cultural, and language, etc), and community resources (private, for-profit, non-profit, and public), and will complement and reinforce one another to reduce disparities.

f) Health care setting activities such as:

Conducting assessments for the delivery of covered benefits, both for use within the clinical setting, and for analysis by benefits managers/sub-contracted third parties; providing patient education and counseling to in*crease* healthy eating habits and physical activity; providing patient individual or group counseling or onsite health promotion activities to assist with making and maintaining lifestyle changes; training health professionals on how to identify and treat obese and overweight individuals; creating a healthy hospital environment such as highlighting healthy choices, counter-advertising for unhealthy choices, providing nutrition standards for food venues and procurement policies, using point of decision strategies for food venues and stairwells, using pricing incentives to

reward healthy choices.

Research and practice-tested strategies that address key obesity-related nutrition and physical activity, such as: evidence-supported environmental strategies for nutrition, physical activity and obesity prevention interventions (http://www.center-trt.org/index.cfm?fa=op.overview), 5210 (http://www.aap.org/obesity/index.html), the 321-Blast Off! (http://www.bluekids.org/teensandkids/3210home.asp), and We Can! (http://www.nhlbi.nih.gov/health/public/heart/obesity/wecan/health-professionals/index.htm).

g) Age-appropriate setting activities:

Integrate demonstration strategies and activities with existing activities including policy implementation and environmental approaches in childcare, school, and other relevant community settings.

Build upon existing age-appropriate child care-based activities (for example): improve the food environment through use of regulations and/or rigorous nutrition standards, improve physical activity standards, and restrict television and screen time viewing; establish and carry out multi-component interventions, including NAP SACC, Eat Well Play Hard, Color Me Healthy, I am Moving, I am Learning; link of relevant childcare resource and referral agency guidance and materials to facilities for assistance and training; provide community support and recognition of childcare facilities that are successful in carrying out improvements for healthy eating, active living.

Build upon existing age-appropriate school-based activities such as: a plan to address key school components encouraged by CDC (http://www.cdc.gov/healthyyouth/keystrategies/pdf/make-a-difference.pdf) including strengthening nutrition and physical activity policies (http://www.fns.usda.gov/tn/Healthy/wellnesspolicy.html; http://www.iom.edu/Reports/2007/Nutrition-Standards-for-Foods-in-Schools-Leading-the-Way-toward-Healthier-Youth.aspx); implement educational curricula and intervention programs designed to promote healthy eating behaviors and habits in youth during the school day and in aftercare and after hour programs including SPARK, CATCH, Hip Hop to Health Jr.; provide training to educational and school support staff professionals demonstrating how to promote a healthy lifestyle and a healthy school environment for children.

h) Evaluation research design:

1. Rigorous pre- (baseline) and post-assessment (12-month follow-up to the baseline) intervention evaluation research design must be used at a minimum. Other experimental or quasi-experimental research designs, including individual or group randomization or comparisons to other ongoing surveillance systems or databases can be proposed.

2. Use robust and efficient clinical and data acquisition and sharing process whereby data elements critical to the research design can be effectively gathered on all participants *and* shared with the Evaluation Center in a timely fashion and in compliance with federal wide assurance requirements. Examples of robust and efficient approaches might include use of technologies such as computer generated systems for assessments and efficient tailored feedback and ongoing support, and use of electronic health records for data acquisition.

3. Outcomes include:

    a. Beneficiary satisfaction with health care services.

b. Quality of life.

c. Appropriate use of strategies and services for which medical assistance is available through child health assistance under the State CHIP plans.

d. Health outcomes including short- and intermediate outcomes including obesity-related behaviors such as increased fruit and vegetable consumption, physical activity, and sleep, and reduced television and passive screen time viewing and consumption of sugar drinks and high calorie dense foods and snacks, parental knowledge and parenting strategies and longer term outcomes including weight change.

Specific expected measurable outcomes:

Based on previous interventions related to fruit and vegetable consumption the expected achievable outcome change would be approximately an increase in 0.3 daily servings. Changes in physical activity behavior could include changes in moderate or vigorous physical activity such as those found in school-based programs, for example an expected net increase in the amount of physical education class time spent in moderate-vigorous activity of 50%, and/or a net increase in the percentage of class time in moderate-vigorous activity of 10%. Health outcomes including longer term weight-related measures, include changes in BMI. The expected 2-year outcome change in BMI z-score would be -0.2 based on experience of other multi-sector interventions.

4. Measures:

- The identification, through interview, survey and other data collection methods, changes in policies and environment and their implementation, services, setting and community policy and environmental changes, implementation and outcomes (e.g. changes in sidewalks, healthy food availability, foods and beverages served to children in childcare and aftercare, screentime policies, unhealthy food advertising and marketing in youth settings), and individual outcomes.

- Quantifiable community or sector measures can, for example, include those provided in the CDC Recommended Strategies and Measurements to Prevent Obesity in the United States (http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5807a1.htm). For example, policy adoption or successful policy implementation would be an expected policy outcome.

- Expected individual outcome achievements include in general a relative 2.5 percentage point change from baseline over the two year intervention period based on a target setting method used in population-based public health; however, effect sizes may be dependent on community participant baselines and intensity of specific intervention components.

5. Plan for linking and coordination across the multiple levels and sectors in order to provide an integrated intervention with consistent strategies. This would include, but not be limited to, infrastructure and management of activities such as a demonstration project coordinator. Coordination includes partner activities, communications, referrals, and reporting. Attention in design should include policies that create environments that support the interventions in the demonstration projects. Attention could also be given to linking community and clinical systems, improving information flow and exchange, engaging and empowering the consumer and the community, increasing access to individual and population health interventions, impacting local and/or State policies directly and indirectly, and providing consistent messaging across the interventions.

6. Implementation: The implementation plan should include:

    a. A detailed timeline, including realistic and measureable milestones.

    b. A staffing plan that defines the roles and responsibilities of Research Team members and other consortium/collaborative partners for activities leading to the accomplishment of milestones.

    c. A management and coordination approach and plan for the Research Team and consortium/collaborative partners.

    d. Quarterly budget plan that is linked to activities and milestones.

Evaluation Center Research Objectives (Component B):

The research plan should include:

1. Plan for the overall evaluation. The overall evaluation plan should be consistent with that of an impact evaluation design. A detailed plan for the design and implementation of the overall evaluation with funded Demonstration Projects and CDC that determines whether programs similar to the awarded demonstration projects should be implemented nationally for children in diverse communities who are eligible for services under Title XXI including:

    a. A timeline

    b. A coordination and communication approach for working with CDC and the demonstration projects

2. Plan for evaluating the Demonstration Projects. A detailed plan for collaborating with the Demonstration Projects and CDC to develop, coordinate, and conduct community-specific evaluation research approaches and protocols to systematically assess the effectiveness of the research Demonstration Projects across projects. This plan should include:

    a. Use of consistent methods such as standardized tools to collect consistent cross-site data and information.

    b. Use of cross-site methods and tools to collect community-specific data and information. Tools that are compatible across demonstration projects and Use of existing surveillance systems and data collection systems and instruments is preferred when appropriate. However, this evaluation will require collection of primary data for process and outcome evaluation. It is anticipated that demonstration project staff in each community will collect and provide data to the Evaluation Center.

    c. Consider the design and implementation of pre- and post-key informant interviews within each demonstration project community. These interviews could, for example, include perceptions about environmental supports, community readiness and capacity.

    d. Provide a comprehensive process evaluation, a rigorous outcome or impact evaluation, and cost-effectiveness, cost savings, and scalability analyses. Examples of evaluation research questions might include:

        i. Process (implementation): Were project activities implemented as originally intended?

        ii. Outcome or impact (effectiveness): Is the program achieving its intended outcomes, goals and objectives in the short-, and medium- term including

health outcomes?

iii. Efficiency: Are project activities conducted with appropriate use of resources such as budget and staff time?

iv. Cost effectiveness: What is the cost of the value or benefit of achieving project goals and objectives with the demonstration projects?

v. Attribution: Can progress on goals and objectives be related to project activities, rather than to concurrent external factors?

vi. Scalability: Is the proposed project suitable for wide implementation in order to reduce the incidence of childhood obesity in the general population of children who are eligible for CHIP?

vii. Sustainability: Can the proposed project activities be sustained by the community beyond the end of the funding period for the demonstration project?

e. Describe plans for serving as the evaluation research data repository for the overall evaluation research of this initiative and the demonstration projects' evaluation research.

f. Describe the approach to be used to compile and analyze data and information; distill evaluation research findings; and interpret these findings in support of (1) national policy decision-making and (2) local community decision-making to solidify, sustain, and expand the programs.

g. Describe plans for producing reports: Interim progress reports and a final report, as well as technical reports, policy briefings, professional presentations, and publications that will be produced collaboratively with funded Demonstration Projects and CDC.

Appendix

Do not use the appendix to circumvent page limits. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide, with the following modifications:

- No publications or other printed material, with the exception of pre-printed questionnaires or surveys, may be included in the Appendix.
- Up to 10 appendices may be included in the application. Appendices may not exceed 60 pages total. Any pages beyond 60 in the appendices may not be reviewed by the Scientific Merit Review panel members.

3. Submission Dates and Times

Part I. Overview Information contains information about Key Dates. Applicants are encouraged to submit in advance of the deadline to ensure they have time to make any application corrections that might be necessary for successful submission.

Organizations must submit applications via Grants.gov, the online portal to find and apply for grants across all Federal agencies. Applicants must then complete the submission process by tracking the status of the application in the eRA Commons, NIH's electronic system for grants administration.

Applicants are responsible for viewing their application in the eRA Commons to ensure accurate and successful submission.

Information on the submission process is provided in the SF424 (R&R) Application Guide.

Note: HHS/CDC grant submission procedures do not provide a period of time beyond the grant application due date to correct any error or warning notices of noncompliance with application instructions that are identified by Grants.gov or eRA systems (i.e. error correction window). The application package is not complete until it has passed the Grants.gov/eRA Commons validation process. This process and email notifications of receipt and validation or rejection may take two (2) business days. Applicants are strongly encouraged to allocate additional time prior to the submission deadline to submit their applications and to correct errors identified in the validation process. Applicants are encouraged also to check the status of their application submission to determine if the application packages are complete and error-free. Applicants who encounter system errors when submitting their applications must attempt to resolve them by contacting the Grants.gov Contact Center (1-800-518-4726; support@grants.gov). If the system errors cannot be resolved, applicants must contact PGO TIMS for guidance at least 3 calendar days before the deadline date.

4. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review.

5. Funding Restrictions

All HHS/CDC awards are subject to the terms and conditions, cost principles, and other considerations described in the HHS Grants Policy Statement.

Pre-award costs are allowable only as described in the HHS Grants Policy Statement.

6. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the SF 424 (R&R) Application Guide. PAPER APPLICATIONS WILL NOT BE ACCEPTED.
Applicants must complete all required registrations before the application due date. Section III. Eligibility Information contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit Applying Electronically.

> **Important reminders:**
> All PD/PIs must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF 424(R&R) Application Package**.** Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to CDC.
>
> The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the Central Contractor Registration (CCR). Additional information may be found in the SF424 (R&R) Application Guide.
>
> See more tips for avoiding common errors.

Upon receipt, applications will be evaluated for completeness by the CDC Procurement and Grants Office (PGO) and responsiveness by PGO and the Center, Institute or Office of the CDC. Applications that are incomplete and/or nonresponsive will not be reviewed.

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. As part of the CDC mission, all applications submitted to the CDC in support of public health research are evaluated for

scientific and technical merit through the CDC peer review system.

Overall Impact

Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance

To what extent does the applicant demonstrates their reach into the eligible pool of children for this FOA identified by including a catchment area, which would include in a rigorous pre-post design of at least 1500 children: (1) low income children eligible for services under titles XIX and XXI of the Social Security Act; (2) children and their families living at least 150% or higher federal poverty level; or (3) catchment areas where 50% of students are in schools eligible for the National School Lunch Program?

For Component A:

Does the applicant specifically design a project that includes a target area of intervention where the average poverty rate is at least 150% or higher of the average poverty rate in the State involved?

To what extent does the applicant provide adequate documentation as to the poverty level of the proposed target area?

To what extent does the applicant address medically underserved children aged 2-12 years and systems changes to promote behavioral counseling for families and their children, and linkages to appropriate activities in health care delivery settings, child care and school settings, and other appropriate community organizations and resources related to childhood obesity?

To what extent does the applicant address use of research and practice-tested strategies that address key obesity-related behaviors and environments including nutrition and physical activity?

To what extent does the applicant cite published and peer-reviewed research demonstrating that the activities proposed to be carried out have been shown to be effective?

For Component B:

To what extent does the applicant demonstrate how they will evaluate the improved communication and linkages to support children and their families between the key areas of health care, community health workers and childcare, school and other community settings?

To what extent does the applicant demonstrate success in conducting complex multi-site evaluative research that results in changes in behavior as well as policy, systems, and environmental changes in organization settings and the community that support population-based changes in health behaviors?

To what extent does the evaluation grant applicant identify the elements to determine if delivery and utilization of care were improved?

Investigator(s)

Are the PD/PIs, collaborators, and other researchers well suited to the project? Have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; is their leadership approach, governance and organizational structure appropriate for the project?

Component A:

To what extent does the PI have experience leading a multi-disciplinary team that is highly interactive with multiple community partners?

To what extent does the PI have experience in being part of a complex public health intervention involving multiple settings that resulted in the adoption of sustainable public health interventions?

To what extent do the research team members (e.g. project manager, evaluator, health educator, community organizer, policy analyst, content experts in nutrition, physical activity, and obesity, and/or others) demonstrate a track record of working together successfully on complex projects that resulted in policy, systems and programmatic public health-related changes that were evaluated, documented, and published?

To what extent does the PI demonstrate experience in successfully applying for funds to carry out activities that seek to promote individual and community health and to prevent the incidence of chronic disease?

Does the research team have experience, and provide evidence of convening and guiding community coalitions or consortia such that milestones and deliverables are completed on schedule for public health related projects?

Is the time commitment of key research team members adequate to successfully design and implement the project?

To what extent does the applicant provide a management plan, a detailed time line, and delineation of roles?

Component B:

To what extent does the PI demonstrate expertise in leading major research and evaluation studies in obesity prevention and control, or related research, with health care settings, community health workers, community organizations, child care and school settings, or other similar settings, organizations, and partners?

To what extent do the PI and the project team (e.g. evaluation expert, project manager, data management and analysis, economist, policy analyst, content experts in nutrition, physical activity, and obesity, and others) document a strong track record of working together on complex public health research and disseminating findings?

To what extent do the PI and the project team have experience in collaborating with other partners in a multi-site study that included a common protocol, development of methods and procedures, including mixed-method community needs assessments, cost effectiveness and scalability analyses, design of instruments, collection, analyses and interpretation of data, and dissemination of results?

Did the applicant provide evidence of previous collaborations with other institutional partners in the form of letters of support, publications, reports, and abstracts?

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches, methodologies, instrumentation, or interventions novel to one field of

research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Component A:

Does the applicant specify use of the Obesity Chronic Care Model in their design and implementation plan?

To what extent does the applicant address and include all key aspects of a childhood obesity prevention and control model including: (1) the components of the Obesity Chronic Care Model; (2) identifying, through self-assessment, behavioral risk factors for obesity among children; (3) identifying, through self-assessment, needed clinical preventive and screening benefits among those children identified as target individuals on the basis of such risk factors; (4) providing ongoing support to such target individuals and their families to reduce risk factors and promote the appropriate use of preventive and screening benefits; (5) improving health outcomes, satisfaction, quality of life, and appropriate use of items and services for which medical assistance is available under title XIX or title XXI among such target individuals; and, (6) promoting changes at the policy, system and environmental levels to promote healthy lifestyles and behaviors among the target group of children and their families.

To what extent does the applicant show their ability to implement a project that draws upon promising, innovative models and incentives to reduce behavioral risk factors while addressing multiple levels of intervention including individual, family, organization, community and policy?

To what extent does the applicant address their ability to integrate existing activities, systems, policies, and/or environmental change that is occurring in health care, child care facilities, schools (including aftercare), and other key community settings?

Does the applicant provide documentation that it will carry out programs and activities that seek to accomplish Healthy People goals set by the State in which the project will be carried out?

To what extent does the applicant plan to assess policy and environmental change in multiple settings?

To what extent does the applicant identify and propose to train, deploy and integrate community health workers into the health care delivery system?

To what extent does the applicant demonstrate both the ability of community health workers to provide direct education and counseling such as effective parenting strategies as well as linkage to social support groups and community resources for nutrition and physical activity?

To what extent does the applicant demonstrate their ability to build upon existing federal and non-federal funding and resources in the catchment area such as to not duplicate efforts but to leverage and build upon existing activities in support of childhood obesity?

To what extent does the applicant address the ability to have a robust clinical and community data acquisition process?

To what extent does the applicant provide sustainability plans to continue and extend successful project activities after this grant?

Component B
To what extent does the applicant address the ability to manage qualitative and quantitative data from the multiple levels and sectors as part of the complex evaluation?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks

for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

Component A:
To what extent does the applicant include a community and settings assessment that shows current gaps, barriers, and opportunities such as 1) existing federal and nonfederal funding efforts; 2) assessment of policies, environments, and activities that address improved nutrition and physical activity in the multiple sectors; 3) current community-wide partnerships or consortia engaged in obesity prevention and control, 4) the health literacy level of the population to address, and 5) the current behavioral risk factors for obesity and attitudes among the population of underserved children and their families?

Does the applicant describe and document a network of partnerships with health care, community health workers, health departments, child care and school settings, and other relevant community- based organizations? Does the applicant document the commitment and contributions of proposed partners?

To what extent has the applicant provided a project plan that demonstrates multisectoral and cooperative conduct that includes a broad range of stakeholders?

Does the applicant demonstrate that a sufficient network of community health workers can be expeditiously utilized to perform the research project within the required time frame? Are community health workers integrated into the intervention strategy?

Does the applicant provide evidence of effective and efficient recruitment and retention of children and parents who are representative of racial/ethnic minorities and socio-economically disadvantaged populations that are disproportionately affected by obesity or related health risk factors?

To what extent does the applicant address and justify the study design as either a rigorous pre-post design or use other experimental approaches such as randomization?

To what extent does the applicant draw upon promising and innovated models and incentives to assess reductions in behavioral risk factors?

To what extent does the applicant address environmental and policy outcomes in the community, child care, school, and clinic settings (e.g.) and the following individual outcomes (beneficiary satisfaction with health care services, quality of life, appropriate use of strategies and services available through child health assistance, and health outcomes including parent and child outcomes)?

Is the sample size adequate and is the study adequately powered to detect intervention effects?

Is there sufficient evidence and justification that the effect size can be achieved through the proposed intervention in the allotted time in the proposed study population?

Are the statistical analyses appropriate for the design and unit of randomization selected?

Does the applicant provide a robust intervention strategy that realistically deploys CHWs, that also incorporates the behavioral assessment done by the health care provider through use of individual and group sessions for counseling and follow-up with parents and their children?

Does the applicant provide a plan to integrate or augment existing activities in childcare, school, and other key community settings?

Does the application address policy, systems, environmental, educational, communications and coordination changes that are robust enough to plausibly result in changes in parental and child behaviors related to childhood obesity?

Does the applicant's community assets and needs assessment plan provide a means to identify resources and gaps related to obesity prevention and reduction with an emphasis on supportive systems, policies and environmental change that support nutrition and physical activity?

Does the applicant specify how they will integrate this project with existing federal and non-federal obesity-related resources and activities?

Does the applicant demonstrate non-financial commitment and agreement from the state Medicaid/CHIP agency?

Does the applicant provide a plan for disseminating evaluation findings and recommendations to various stakeholders the other project grantees, CDC, and local coalition and community?

Component B:
To what extent does the applicant demonstrate expertise and experience in designing, implementing and analyzing evaluations of multi-site public health programs?

To what extent does the applicant demonstrate an ability to work collaboratively and effectively with federal government agencies and with a diverse range of State, local and community entities in the evaluation of public health programs?

To what extent does the evaluation applicant have a detailed plan for working with the project demonstration grantees to develop a common set of evaluation questions, design and methods, instruments and tools?

Does the evaluation applicant submit a plan for working with the project demonstration grantees to obtain common measures, manage the data including quality control, and a plan for aggregation and synthesis?

Does the plan utilize the CDC Framework for Evaluation in Public Health (refer to: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr4811a1.htm)?

To what extent does the evaluation applicant submit a feasible work plan and timeline that coordinates the work of all grantees in support of the overall evaluation?

Does the applicant provide potential indicators and data collection methods for a thorough process evaluation that will carefully track all aspects of the intervention implementation?

Does the applicant provide a plan for disseminating evaluation findings and recommendations to various stakeholders including the project demonstration grantees, CDC and other federal agencies?

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Is there adequate infrastructure for the coordination of the project across the various sectors? Is there evidence of established or prior working relationships with proposed partner organizations and entities (e.g. Memorandum of Agreement, Memorandum of Understanding, other governance documents, letters of support, citation for reports that document the contributions of each party)? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Component A:

To what extent does the application include documentation of the active engagement and a long-term commitment of organizations that are part of the multi-sectoral coalition or consortium that includes, at a minimum, the core sectors in this FOA (health care, schools, childcare, and other key community settings), including information provided in Appendix 1?

To what extent does the applicant demonstrate a track record of working with partners successfully on complex projects that resulted in policy, environmental, systems and programmatic public health-related changes that were evaluated, documented, and published?

To what extent does the applicant's organization document that findings from this project can be adopted as new policies, practices and services for sustainability and/or scalability?

To what extent does the applicant indicate their plan to share data with the Evaluation Center as part of the overall evaluation?

Component B:

To what extent does the PI and project team document a strong track record of working together on complex public health evaluation research and disseminating findings and synthesized results?

To what extent does the PI and the project team have experience in collaborating with other partners in a multi-site study, with multiple levels of intervention, that included a common protocol, development of methods and procedures, including mixed-method community needs assessments, cost effectiveness and scalability analyses, design of instruments, collection, analyses and interpretation of data, and dissemination of results?

Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact/priority score, but will not give separate scores for these items.

Protections for Human Subjects

For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the HHS/CDC Requirements under AR-1 Human Subjects Requirements.

Inclusion of Women, Minorities, and Children

When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children. For additional information on review of the Inclusion section, please refer to the Inclusion of Women and Racial and Ethnic Minorities in Research.

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the

appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section.

Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Renewals

For Renewals (formerly called competing continuation applications), the committee will consider the progress made in the last funding period.

Revisions

Revisions (formerly called competing supplement applications), are a request for an increase in support in a current budget period for expansion of the scope of the approved project or program or to meet an unforeseen increase in costs. The request may specify budgetary changes required for the remainder of the project period as well as for the current budget period. Supplemental applications requesting a programmatic expansion (change in scope) must undergo objective review and generally are required to compete for support; requests for administrative supplements may be awarded without objective review or competition.

Additional Review Considerations

As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact/priority score.

Resource Sharing Plans

HHS/CDC policy requires that recipients of grant awards make unique research resources and data readily available for research purposes to qualified individuals within the scientific community after publication. Please see: http://www.cdc.gov/od/foia/policies/sharing.htm. Investigators responding to this funding opportunity should include a plan on sharing research resources and data.

Budget and Period of Support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research; adjustments to the cooperative agreement may be made based on the recommendations of the reviewers.

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by an appropriate peer review group, in accordance with CDC peer review policy and procedures, using the stated review criteria.

As part of the scientific peer review, all applications may:

- Undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review), will be discussed and assigned an overall impact/priority score.
- Receive a written critique.

Applications will be assigned to the appropriate HHS/CDC Center, Institute, or Office. Applications will compete for available funds with all other recommended applications submitted in response to this FOA. Following initial Scientific Merit peer review recommended applications will receive pre-

decisional CDC site visits to more fully understand and validate the capacity of the recommended applicant communities between May-June, 2011. Following pre-decisional site visits, recommended applicants will receive a second level of review. The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.
- Results of the Pre-decisional Site Visits.
- Geographic diversity of study sites.
- Diversity in populations disproportionately impacted by obesity-related risk factor and obesity (e.g., racial and ethnic minorities or low socioeconomic status populations).
- Diversity in intervention approaches.
- Non-Federal cash and/or in-kind contributions included in the application in relationship to sustaining successful demonstration project activities.

3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the eRA Commons.

Information regarding the disposition of applications is available in the HHS Grants Policy Statement.

Section VI. Award Administration Information

1. Award Notices

If the application is under consideration for funding, HHS/CDC will request "just-in-time" information from the applicant as described in the HHS Grants Policy Statement.

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the grants management officer is the authorizing document and will be sent via email to the grantee business official.

Awardees must comply with any funding restrictions described in Section IV.5. Funding Restrictions. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs specified in the FOA document.

2. Administrative and National Policy Requirements

All HHS/CDC grant and cooperative agreement awards include the HHS Grants Policy Statement as part of the NoA. For these terms of award, see the HHS Grants Policy Statement Part II: Terms and Conditions of Award, Overview of Terms and Conditions of Award and Requirements for Specific Types of Grants. Additional requirements are available at the following internet address: http://www.cdc.gov/od/pgo/funding/ARs.htm.

Cooperative Agreement Terms and Conditions of Award

The following special terms of award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of Health and Human Services (DHHS) grant administration regulations at 45 CFR Parts 74 and 92 (Part 92 is applicable when State and local Governments are eligible to apply), and other HHS, PHS, and CDC grant administration policies.

The administrative and funding instrument used for this program will be the cooperative agreement, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial CDC programmatic involvement with the awardees is anticipated during the performance of the activities. Under the cooperative agreement, the HHS/CDC purpose is to support and stimulate the recipients'

activities by involvement in and otherwise working jointly with the award recipients in a partnership role; it is not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardees for the project as a whole, although specific tasks and activities may be shared among the awardees and HHS/CDC as defined below.

Recipient Rights and Responsibilities

Component A

The PD(s)/PI(s) will have the primary responsibility for:

1. Designing, conducting and implementing the intervention demonstration project research plan to address the described research objectives of this cooperative agreement.

2. Guiding and coordinating the work of the coalition and ensuring effective linkage, communication, and accountability.

3. Collaborating with the Evaluation Center and other Demonstration Project grantees and CDC.

4. Sharing surveys and other data collection instruments, data, and evaluation information during and post-information with the other Demonstration Project grantees, the Evaluation Center, and CDC.

5. Obtaining the appropriate Institutional Review Board approvals for research involving human subjects.

6. Participating in CDC-sponsored meetings as scheduled by the Demonstration project grantees, the Evaluation Center and CDC.

7. Conducting analyses, interpreting results, and disseminating findings in peer-reviewed journals, technical reports, research and policy briefs, presentations at professional and scientific conferences and policy forums, as appropriate, and contributing scientific findings to appropriate Web sites or other channels for sharing findings.

8. Make use of local analytic support, center-specific and shared datasets and local resources related to the project.

9. The Principal Investigator will attend at least one in-person meeting per year and televideo conference calls regularly, as scheduled in consultation with CDC.

10. Other members of the research team will participate in appropriate sub-committees and CDC-sponsored meetings.

11. Ensure adequate management, staffing, oversight, and mentoring of research team members in support of the project activities.

Awardees will retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current DHHS, PHS, and CDC policies.

Component B

1. Designing, conducting and implementing the overall evaluation plan to address the described research objectives of this cooperative agreement.

2. Collaborating with and assisting demonstration project grantees, in consultation with CDC, in the designing, conduct, implementation, analysis, interpretation, and reporting of Demonstration Project evaluations.

3. Sharing surveys and other data collection instruments with the demonstration project grantees and CDC and serving as the data repository for the overall evaluation.

4. Obtaining the appropriate Budget and Institutional Review Board approvals for research involving human subjects.

5. Conducting aggregate analyses, interpreting results, and disseminating findings in peer-reviewed journals, technical reports, research and policy briefs, presentations at professional and scientific conferences and policy forums, as appropriate, and contributing scientific findings to appropriate Web sites or other channels for sharing findings.

6. The Principal Investigator will attend at least one in-person meeting per year and televideo conference calls regularly, as scheduled in consultation with CDC.

7. Other members of the evaluation project team will participate in appropriate subcommittee and CDC-sponsored meetings.

8. Ensure adequate management, staffing and oversight of the project team in support of the project activities.

Awardees will retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current DHHS, PHS, and CDC policies.

HHS/CDC Responsibilities

CDC staff have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below:

There are two separate CDC scientific roles – Scientific Collaborator (SC) and the Scientific Program Official (SPO).

In this cooperative agreement, a NCCDPHP SC is an equal partner with scientific and programmatic involvement during the conduct of the project through technical assistance, advice, and coordination. The SC will:

1. Provide expertise and guidance on the project-developed protocol including use of evidence-informed strategies and implementation approaches to ensure multi-site cohesion as part of the overall evaluation approach.

2. Provide expertise related to data collection methods, instruments and tools to aid in standardization across the multiple sites.

3. Support grantee activities in intervention design, data management, data analysis and interpretation, formats for presenting research findings, and in comparing project-developed evaluation formats with other research projects and activities known to CDC.

4. Provide scientific consultation and technical assistance on epidemiology, evaluation, statistical calculations, and data storage and tracking formats used in other CDC-sponsored research that could be advantageous to the project.

5. Assist in the analyses, interpretation, and reporting of findings in the literature, summary and policy briefs, and professional presentations.

Additionally, an HHS/CDC NCCDPHP Project Officer or other HHS/CDC staff will provide day-to-day programmatic, administrative, and fiscal management in support of the project as defined above. Additionally, an HHS/CDC agency scientific program official (SPO) will be responsible for the normal scientific and programmatic stewardship of the award. The SPO will be:

1. Named in the NoA as the Program Official to provide overall scientific and programmatic stewardship of the award.

2. Serve as the primary point of contact on official award-related activities; including an annual review of the grantee's performance as part of the request for continuation application.

3. Approve requests for changes in scope, objectives, and or budget that deviate from the approved peer-reviewed application.

4. Carry out continuous review of all activities to ensure objectives are being met.

5. Attend committee meetings and participate in conference calls for the purposes of assessing overall progress, and for program evaluation purposes.

6. Monitor performance against approved project objectives.

Areas of Joint Responsibility

Components A and B

The Demonstration Project Research Network Committee will be formed after grantees are awarded and made up of a Principal Investigator from each funded Demonstration Project, the Evaluation Center grantee, and the lead HHS/CDC Project Scientist and Project Administrator. Other federal agency liaisons such as a Senior Advisors from HHS (HRSA, NIH, CMS) may be appointed as a member. This Committee will come to a working consensus on common evidence-informed strategies, common indicators/data elements and methods; collaboratively establish research, publication, and presentation priorities; and establish policies and procedures that govern the analysis, research and translation work of the research network.

Each full member will have one vote. The HHS/CDC will have only one vote. Awardees or members of the Research Network Committee will be required to accept and implement policies approved by the Research Network Committee.

Funded Demonstration Sites should seek the review and input from their state Medicaid/CHIP agency, and as warranted from the Federal CMS, as well as technical input from CDC when identifying and considering the adoption of innovative interventions that have long-term financial and operational implications for CMS.

3. Reporting

1. When multiple years are involved, awardees will be required to submit the Non-Competing Continuation Grant Progress Report (PHS 2590) annually and financial statements as required in the HHS Grants Policy Statement (so less than 120 days prior to the end of the current budget period).
2. An annual report no more than 90 days after the end of the budget period.
3. Financial Status report, not more than 90 days after the end of the budget period.
4. A final progress report, invention statement, and Financial Status Report are required when an award is relinquished when a recipient changes institutions or when an award is terminated, no more than 90 days after the end of the project period.

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Scientific/Research Contact(s)

Michael Dalmat, Dr.P.H.
National Center for Chronic Disease Prevention and Health Promotion
Extramural Research Program Office
Centers for Disease Control and Prevention
4770 Buford Hwy., NE Mailstop K-92
Atlanta, GA 30341
Tel 770 488 6423
Email: Mdalmat@cdc.gov

Peer Review Contact(s)

Donald Blackman, Ph.D.
National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) Telephone: (770) 488-3023
Email: Dyb7@cdc.gov

Financial/Grants Management Contact(s)

Shicann Phillips, Grants Management Specialist
U.S. Department of Health and Human Services
Centers for Disease Control and Prevention
Procurement and Grants Office
2920 Brandywine Road MS-K75
Atlanta GA 30341
Telephone: 770-488-2615
Email:SPhillips2@cdc.gov

Application Submission Contacts

Grants.gov Customer Support (Questions regarding Grants.gov registration and submission, downloading or navigating forms)
Contact Center Phone: 800-518-4726
Email: support@grants.gov
Hours: 24 hours a day, 7 days a week; closed on Federal holidays

eRA Commons Help Desk(Questions regarding eRA Commons registration, tracking application status, post submission issues)
Phone: 301-402-7469 or 866-504-9552 (Toll Free)
TTY: 301-451-5939
Email: commons@od.nih.gov
Hours: Monday - Friday, 7am - 8pm Eastern Time

CDC Technical Information Management Section (TIMS)
Procurement and Grants Office
Telephone 770-488-2700
Email: mailto:PGOTIM@cdc.gov
Hours: Monday - Friday, 9am - 5pm Standard Time

Section VIII. Other Information

All awards are subject to the terms and conditions, cost principles, and other considerations described in the HHS Grants Policy Statement.

Authority and Regulations

Awards are made under the authorization of Sections 301,311 and 317 (C) of the Public Health Service Act as amended, and under Federal Regulations (42 U.S.C., Sections 241, 243 and 237b-4) as amended.

Section 401(a) of The Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA, P.L. 111-3), added new section 1139A, to the Social Security Act (the Act). Subsection 1139A(e) of the Social Security Act requires the Secretary of Health and Human Services (HHS) to conduct a Childhood Obesity Demonstration Project (http://www.ssa.gov/OP_Home/ssact/title11/1139A.htm). In 2010, the Patient Protection and Affordable Care Act (ACA) appropriated funding for the Project in section 4306.

Federal Citations

CDC Grants General Information
http://www.cdc.gov/od/pgo/funding/grants/grantmain.shtm

Use of Animals in Research:
http://www.cdc.gov/od/science/integrity/acupo/

SF424: Part III, Section 2.2

Human Subjects Protection:

http://www.cdc.gov/od/science/integrity/hrpo/

SF424: Part III, Section 2.1

Data and Safety Monitoring Plan:
http://grants.nih.gov/grants/guide/notice-files/not98-084.html
SF424: Part II, Section 4.1.5

Sharing Research Data:
http://www.cdc.gov/od/foia/policies/sharing.htm#viii
http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_Adobe_VerB.pdf#page=260
SF424: Part III, Section 4.5

Policy for Genome-Wide Association Studies (GWAS):
http://grants.nih.gov/grants/gwas/
SF424: Part III, Section 1.5.3

Sharing of Model Organisms:
http://grants.nih.gov/grants/policy/model_organism/index.htm
SF424: Part III, Section 1.5.2

Inclusion of Women and Racial and Ethnic Minorities in Research:
http://www.cdc.gov/maso/Policy/Inclusion%20of%20Women%20and%20Racial%20and%20Ethnic%20Minorities%20in%20Research10-18-2007.pdf

SF424: Part II, Section 4.2

Inclusion of Persons Under the Age of 21 in Research:
http://www.cdc.gov/maso/Policy/Inclusion%20of%20Women%20and%20Racial%20and%20Ethnic%20Minorities%20in%20Research10-18-2007.pdf

SF424: Part II, Section 4.4

Publications:
HHS Grants Policy Statement (Intellectual Property-Rights in Data & Publications)

Health Insurance Portability and Accountability Act Requirements:
http://www.cdc.gov/mmwr/preview/mmwrhtml/m2e411a1.htm

SF424: Part III, Section 4.2

URLs in HHS/CDC Grant Applications or Appendices:
SF424: Part I, Section 4.2

Healthy People 2020:
http://www.health.gov/healthypeople

Authority and Regulations:
HHS Grants Policy Statement

Smoke-Free Workplace:
http://www.cdc.gov/Features/Smoke-FreeAir
Public Law 103-227
Pro-Children Act of 1994.
SF424: Part III, Section 2.11

HIV/AIDS Confidentiality Provisions
http://www.cdc.gov/hiv/

HIV Program Review Panel
http://www.cdc.gov/hiv/strategic_planning/epr_report/

Patient Care
http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5210a1.htm

Executive Order 12372 Review
http://www.cdc.gov/about/business/funding.htm

Public Health System Reporting
http://www.cdc.gov/DataStatistics/

Paperwork Reduction Act
http://www.cdc.gov/od/science/integrity/reducePublicBurden/

Lobbying Restrictions
http://www.cdc.gov/dash/grants_mgt/docs_pdfs/GranteesFinancialReference.pdf

Prohibition of Use of CDC Funds for Certain Gun Control Activities
http://www.cdc.gov/about/business/funding.htmhttp://www.cdc.gov/od/pgo/funding/grants/additional_req.2010.04.09.shtm#ar13

Accounting System Requirements
http://www.cdc.gov/od/pgo/funding/grants/additional_req.shtm

Proof of Non-profit Status
http://www.cdc.gov/od/pgo/funding/grants/additional_req.shtm#ar15

Security Clearance
http://www.cdc.gov/od/pgo/funding/grants/additional_req.2010.04.09.shtm#ar16

Peer and Technical Reviews of Final Reports of Health Studies – HHS/ATSDR

http://www.cdc.gov/od/pgo/funding/grants/additional_req.shtm

Cost Recovery – HHS/ATSDR
http://www.cdc.gov/od/pgo/funding/grants/additional_req.shtm

Third Party Agreements – HHS/ATSDR
http://www.cdc.gov/od/pgo/funding/grants/additional_req.shtm

Small, Minority and Women-owned Business
http://www.cdc.gov/od/pgo/funding/grants/additional_req.shtm

Research Integrity
http://www.cdc.gov/od/pgo/funding/grants/additional_req.shtm

Compliance with Executive Order 13279
http://www.cdc.gov/od/pgo/funding/grants/additional_req.shtm

National Historic Preservation Act of 1966 (Public Law 89-665, 80 Stat. 915)
http://www.cdc.gov/od/pgo/funding/grants/additional_req.shtm

Conference Disclaimer and Use of Logos
http://www.cdc.gov/od/pgo/funding/grants/additional_req.shtm